



IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPLICANT: Takeda Pharmaceutical Co., Ltd.

U.S. PATENT NO. 6,939,971

ISSUED: September 6, 2005

TO: FUJISHIMA ET AL.

DATE: October 2, 2009

FOR: BENZIMIDAZOLE COMPOUND
CRYSTAL

FROM: Serial No. 10/655114

FILED: September 4, 2003

EXTENSION FILED: March 26, 2009

ATTORNEY 04164.0013USTE
DOCKET NO.

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this paper is being mailed to the U.S. Patent and Trademark Office on October 2, 2009.

By:

Name: Justine L. Suleski

SUBMISSION OF SUPPLEMENTAL INFORMATION
UNDER 37 C.F.R. § 1.765

Mail Stop: Patent Extension
Commissioner of Patents
Patent Extension
P.O. Box 1450
Alexandria, Virginia 22313-1450

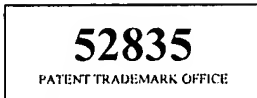
Dear Sir:

Applicant Takeda Pharmaceutical Co., Ltd. hereby submits a copy of relevant pages of Orange Book database of the Food and Drug Administration that indicates that pediatric exclusivity has been allowed to U.S. Patent No. 6,939,971 by the Food and Drug Administration available at

http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022287&TABLE1=OB_Rx,
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022287&Product_No=001&table1=OB_Rx and
http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022287&Product_No=002&table1=OB_Rx. The pediatric exclusivity to the '971 patent was allowed based on the pediatric exclusivity granted to patents relevant to PREVACID®, whose active ingredient is lansoprazole, which is a racemate of dexlansoprazole as described in section (4) on pages 3-4 of the application for extension filed on March 26, 2009.

Applicant respectfully contends that the pediatric exclusivity, which is based on a different statute from 35 U.S.C. § 156, such as § 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a), does not affect Applicant's eligibility for the patent term extension nor the length of the extension because 35 U.S.C. § 156 requires that the term of the patent have never been extended under § 156 (e)(1) and U.S. Patent No. 6,939,971 has never been extended under this section of 35 U.S.C.

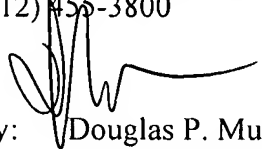
Respectfully submitted,



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Dated: October 2, 2009

DPM/my

By:  Douglas P. Mueller
Reg. No. 30,300

Search results from the "OB_Rx" table for query on "022287."

Active Ingredient:	DEXLANSOPRAZOLE
Dosage Form;Route:	CAPSULE, DELAYED RELEASE; ORAL
Proprietary Name:	KAPIDEX
Applicant:	TAKEDA PHARMS
Strength:	30MG
Application Number:	022287
Product Number:	001
Approval Date:	Jan 30, 2009
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View



Active Ingredient:	DEXLANSOPRAZOLE
Dosage Form;Route:	CAPSULE, DELAYED RELEASE; ORAL
Proprietary Name:	KAPIDEX
Applicant:	TAKEDA PHARMS
Strength:	60MG
Application Number:	022287
Product Number:	002
Approval Date:	Jan 30, 2009
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

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Patent and Exclusivity Search Results from query on Appl No 022287 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
<u>022287</u>	001	5045321	Sep 3, 2008		Y		
<u>022287</u>	001	5045321*PED	Mar 3, 2009				
<u>022287</u>	001	5093132	Sep 3, 2008		Y	<u>U-949</u>	
<u>022287</u>	001	5093132	Sep 3, 2008		Y	<u>U-950</u>	
<u>022287</u>	001	5093132	Sep 3, 2008		Y	<u>U-951</u>	
<u>022287</u>	001	5093132*PED	Mar 3, 2009				
<u>022287</u>	001	5433959	Sep 3, 2008		Y	<u>U-949</u>	
<u>022287</u>	001	5433959	Sep 3, 2008		Y	<u>U-950</u>	
<u>022287</u>	001	5433959	Sep 3, 2008		Y	<u>U-951</u>	
<u>022287</u>	001	5433959*PED	Mar 3, 2009				
<u>022287</u>	001	6462058	Jun 15, 2020	Y	Y	<u>U-949</u>	
<u>022287</u>	001	6462058	Jun 15, 2020	Y	Y	<u>U-950</u>	
<u>022287</u>	001	6462058	Jun 15, 2020	Y	Y	<u>U-951</u>	
<u>022287</u>	001	6462058*PED	Dec 15, 2020				
<u>022287</u>	001	6664276	Jun 15, 2020	Y	Y	<u>U-949</u>	
<u>022287</u>	001	6664276	Jun 15, 2020	Y	Y	<u>U-950</u>	
<u>022287</u>	001	6664276	Jun 15, 2020	Y	Y	<u>U-951</u>	
<u>022287</u>	001	6664276*PED	Dec 15, 2020				
<u>022287</u>	001	6939971	Jun 15, 2020			<u>U-949</u>	
<u>022287</u>	001	6939971	Jun 15, 2020			<u>U-950</u>	
<u>022287</u>	001	6939971	Jun 15, 2020			<u>U-951</u>	
<u>022287</u>	001	6939971*PED	Dec 15, 2020				
<u>022287</u>	001	7285668	Jun 15, 2020	Y			
<u>022287</u>	001	7285668*PED	Dec 15, 2020				

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
<u>022287</u>	001	<u>PED</u>	Jul 30, 2012

022287 **001** **NP****Jan 30, 2012**

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
 2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.
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Patent and Exclusivity Search Results from query on Appl No 022287 Product 002 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
<u>022287</u>	002	5045321	Sep 3, 2008		Y		
<u>022287</u>	002	5045321*PED	Mar 3, 2009				
<u>022287</u>	002	5093132	Sep 3, 2008		Y	<u>U-949</u>	
<u>022287</u>	002	5093132	Sep 3, 2008		Y	<u>U-950</u>	
<u>022287</u>	002	5093132	Sep 3, 2008		Y	<u>U-951</u>	
<u>022287</u>	002	5093132*PED	Mar 3, 2009				
<u>022287</u>	002	5433959	Sep 3, 2008		Y	<u>U-949</u>	
<u>022287</u>	002	5433959	Sep 3, 2008		Y	<u>U-950</u>	
<u>022287</u>	002	5433959	Sep 3, 2008		Y	<u>U-951</u>	
<u>022287</u>	002	5433959*PED	Mar 3, 2009				
<u>022287</u>	002	6462058	Jun 15, 2020	Y	Y	<u>U-949</u>	
<u>022287</u>	002	6462058	Jun 15, 2020	Y	Y	<u>U-950</u>	
<u>022287</u>	002	6462058	Jun 15, 2020	Y	Y	<u>U-951</u>	
<u>022287</u>	002	6462058*PED	Dec 15, 2020				
<u>022287</u>	002	6664276	Jun 15, 2020	Y	Y	<u>U-949</u>	
<u>022287</u>	002	6664276	Jun 15, 2020	Y	Y	<u>U-950</u>	
<u>022287</u>	002	6664276	Jun 15, 2020	Y	Y	<u>U-951</u>	
<u>022287</u>	002	6664276*PED	Dec 15, 2020				
<u>022287</u>	002	6939971	Jun 15, 2020			<u>U-949</u>	
<u>022287</u>	002	6939971	Jun 15, 2020			<u>U-950</u>	
<u>022287</u>	002	6939971	Jun 15, 2020			<u>U-951</u>	
<u>022287</u>	002	6939971*PED	Dec 15, 2020				
<u>022287</u>	002	7285668	Jun 15, 2020	Y			
<u>022287</u>	002	7285668*PED	Dec 15, 2020				

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
<u>022287</u>	002	<u>PED</u>	Jul 30, 2012

022287 002 NP

Jan 30, 2012

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